Supreme Court, U.S.
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92-1289

No. -

In the Supreme Court of the United States

OCTOBER TERM, 1992

JOSE M. OTERO, PRO SE,
PETITIONER,

v.

INTERNATIONAL GENERAL ELECTRIC CO., ET AL.,
RESPONDENTS.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

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QUESTIONS PRESENTED

I. Whether the Court of Appeals for the First Circuit erred in excluding and not acting upon the United States Supreme Court Decision entered on June 24, 1992, *Cipollone* v. *Liggett Group, Inc.*, ____ U.S. ____, 112 S.Ct. 2608, 60 USLW 4703 (1992) as it was a product liability case directly related to the instant case?

II. Whether the Court erred in relying on fraudulent representation or misrepresentation of medical literature by expert witnesses thereby urging a $100,000.00 stipulation?

III. Whether the Court of Appeals should have considered and acted upon the Safe Medical Devices Act?

IV. Whether the Court of Appeals should have used cases superseded by *Cipollone* v. *Liggett Group, Inc.* to support its Judgment of June 29, 1992?

V. Whether a warning or cautionary statement in the FDA statute is applicable to Conray 60 RCM and/or to the device GE CT 9800?

VI. Whether there is an implied right of action under the FDCA?

II

THE PARTIES

The parties to the proceedings below were the Petitioners, Jose Otero Laborde, Elvira Laborde de-Otero, Minerva Otero Laborde and Rene Otero Laborde and the respondents, International General Electric Company and Mallinckrodt Corporation. Jose Otero Laborde is the only petitioner on this petition. [*See also Footnote 1*]

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PETITION FOR WRIT OR CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Petitioner Jose Otero, appearing *pro se* (but not *in forma pauperis)* respectfully prays that a writ of certiorari issue to revise the judgment and opinion of the United States Court of Appeals for the First Circuit, entered in the above entitled case on June 29, 1992.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the First Circuit (Per Curiam) is unpublished but is reproduced at pages A-1 to A-4 of the Appendix to this petition.[4]

The judgment of the District Court for the District of Puerto Rico is unpublished but is reproduced at page A-11 of the Appendix to this petition.

JURISDICTION

On June 29, 1992 the First Circuit affirmed the judgment of the District Court. The First Circuit denied the Petitioner's Motion for Rehearing and motions to supplement the Petition for Rehearing on September 2, 1992. Mandate issued on September 10, 1992. Appellant's motion to Recall Mandate was denied on October 2, 1992. Petitioner's Motion to Extend Time for Filing a Petition for Writ of Certiorari to and including January 30, 1993 was allowed on November 9, 1992.

The Supreme Court of the United States has jurisdiction to review the judgment in question under 28 U.S.C. § 1254.

CONSTITUTIONAL PROVISIONS & STATUTES INVOLVED

CONSTITUTION OF THE UNITED STATES

Amendment I.

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Amendment V.

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, withour due process of law; nor shall private property be taken for public use, without just compensation.

Safe Medical Devices Act is reproduced at Appendix F. The following statutes are reproduced at Appendix G; 15 U.S.C. §1261, 21 U.S.C. §§321, 353, 360 hh, 360j and 31 L.P.R.A. §3018.

STATEMENT OF THE CASE

On February 20, 1987, Jose Otero et al., through his attorney, Francisco M. Lopez-Romo, filed a *"product"* (based on diversity jurisdiction; 28 U.S.C. 1332) *"liability"* action against General Electric Co. and Mallinckrodt Co., manufacturer's respectively, of the GE CT 9800, a machine used to provide sliced scanned views in photos of patient's inner body organs. Because of a particular enhancement necessary to obtain *"better"* views and as a result, better *"photos"*, a R.C.M. Conray 60 radio contrast medium has to be injected not *into* the machine as a lubricator, but *into* the patient ipso facto, any harm done to the patient is because a dye (R.C.M.) has to be injected in order to comply with the requirements of the enhancement phase of the GE CT 9800. As such, Conray 60 R.C.M. becomes an accessory or component of the GE CT 9800.

Upon being subjected to such medical examination, patient Ruben Otero-Laborde, had an *"Anaphylactoid Shock"* and died as a result of the causal interaction of the GE CT 9800 and Conray 60 R.C.M. (Appendix I)

Case # 87-278 (JAF) was held in Federal District Court (U.S.) for Puerto Rico and the Honorable Judge Fuste granted a directed verdict in favor of General Electric.

Mallinckrodt and Jose Otero, et al., entered a $100,000.00 stipulation at the conclusion of all the evidence, *without the jury being aware*, but after the evidence had been *heard* by District Court. District Court refused to allow the case to go to the jury in a *court determination* influenced by all the evidence seen and heard at trial until that specific dismissal point in time.

The Honorable Judge Fuste urged the stipulation after hearing all the evidence, in particular within the framework of *Guevara* v. *Dorsey*, 845 F.2d 364 (1st Cir. 1988), case law decided by the First Circuit Court of Appeals invoked by co-defendant General Electric as well as co-defendant Mallinckrodt. Simply stated, Judge Fuste encouraged and urged the stipulation, unaware of the fraudulent character which was the underlying basis of the evidence presented to him *from* the medical literature, *verbally*, which never reached him as *exhibits* alluded to specifically. Eventually, petitioner discovered the "stipulation" was marred by fraud. (September 13, 1990).

Upon preparing for local case No. 809-87-270, Puerto Rico Superior Court, malpractice case (non-diversity co-defendants) against Hospital and Doctors, petitioner Jose Otero, came up with medical literature which in essence admitted and read to the effect that patients with urticaria pigmentosa (mastocytosis) are hypersensitive and prone to R.C.M. Conray 60% reactions; exactly the essence of plaintiff's expert witness, Dr. Angel Roman Franco's allegations throughout trial (87-278 (JAF)) among other allegations. Medical literature mentioned was written by Dr. Charles Parker and Dr. Bruce McLennan. Lacking diversity jurisdiction against doctors even though Dr. Lazaga was "star witness" for Mallinckrodt and General Electric; in case 87-278 (JAF), diversity jurisdiction wasn't granted by Judge Fuste, nor invoked by plaintiffs, whereby petitioner Otero decided to carry on a full investigation on his own. (It is noteworthy that Attorney Agrait for General Electric, cross-examined Dr. Lazaga, G.E.'s client in a lease plan for the GE CT 9800; his witness). (Trial Transcript)

Co-defendants expert witness further wrote that such "Anaphylactoid" reactions to Conray 60 are of lethal, mortal character and *withheld* said conclusions in their testimonies as expert witnesses in case 87-278 (JAF) District Court, which in *essence* was the main issue at trial, insofar as *"failure to warn"*. (Appendix D) See also Footnote 2.

The same witnesses, however, deemed it wise to deny their findings, on their own medical literature during testimony under oath, to stay within the parameters of *Guevara* v. *Dorsey*, which holds that if the doctor practitioner *"knew" about the cause-effect relationship between the condition (Urticaria Pigmentosa) and sensitivity to R.C.M. Conray 60, there was not and is not, then, a need to include the condition in the "warnings"* of the package insert and the "negligence" would thus fall on practitioner, Dr. Lazaga's, shoulders. Just like that and simple as that. (But see *Cipollone* v. *Liggett Group, Inc.*, 112 S.Ct. 2608, 2623 n.25, 2624 n.28.)

At the same time, another expert witness, Dr. Edward Aten, held for co-defendants, that low osmolality contrast media like, *"Omnipaque"* or *"Hexabrix"* do not necessarily induce better patient treatment than HOCM *(High Osmolality Contrast Media)* like Conray 60. Hexabrix was available on February 21, 1986. Same expert witness testified fraudulently on F.D.A.; HOCM-LOCM, and Urticaria Pigmentosa (Mastocytosis). Hexabrix is a low osmolality contrast medium, also manufactured by Mallinckrodt. (Appendices D & E)

Because co-defendants, with Judge Fuste's authorization brought out the F.D.A. in their testimonies without producing a *"scintilla"* of evidence to prove their allegations insofar as the F.D.A. status of their products, petitioner Otero obtained all F.D.A. (Food and Drug) pre-market approval, clearance and *"absence of final approval"*, pertinent information for the GE CT 9800 (thru Freedom of Information), a device per F.D.A.; and Conray 60, a restricted device per F.D.A. (that) since it is a *"diagnostic drug"* substance in *combination* and *accessorial* to the GE CT 9800 and Petitioner has evidence to that effect from the F.D.A.; nor is specifically the GE CT 9800 approved by the F.D.A. nor R.C.M. Conray 60, per Sect. 510(k) F.D.A. and *"Restricted Devices"*, per F.D.A. 21 U.S.C. § 360j(e)(1) at (A) and (B), as so holds, it is thus included. *(See* House Report No. 101-808, *"Background on Need for the Legislation"*, pg. 14, at 6307.

F.D.A. references by co-defendants were accepted by Judge

Fuste, absent all evidence to the effect. With the alleged evidence for *"fraud upon the Court"* on the part of co-defendants expert witnesses and F.D.A. evidence successfully covered up by defendants in District Court trial, with no supporting evidence whatsoever; F.D.A. evidence which co-defendants brought out spontaneously as a matter of fact; and with Federal Rules of Evidence 803-18 ignored as further supporting evidence, then plaintiff Otero, pro-se, filed a Motion on the basis of F.R.C.P. 60(b)(6) *(fraud upon the court)* to reopen case 87-278 (JAF), including the further allegations of concealment, conspiracy, breach of warranty and *"misrepresentations"* as well as *"fraudulent representation"* of F.D.A., November 28, 1990 amendments, *ante*. See *In Re Bendectin*, 857 F.2d 290 (6th Cir. 1988); *Cipollone* v. *Liggett Group, Inc.*, 112 S.Ct. 2608 (1992).

This *"Motion"* was declared *"Moot"* and *"Matter Decided"* by Judge Fuste in District Court, after Plaintiff's Motion (pro se) was filed timely, on July 18, 1991 per F.R.C.P. 60(B) 6 *at that specific point in time*. (Record on Appeal)

On September 5, 1991 plaintiff-appellant Otero, filed a *"Notice of Appeal"* to the Court of Appeals for the First Circuit, appealing from *"Judgment"* on case 87-278 (JAF), Federal District Court for Puerto Rico. (Record on Appeal)

On June 29, 1992, Court of Appeals affirming District Court *"Orders"* were thus so upheld.

On *"Petition For Rehearing"*, filed on July 1st, 1992, with addendums prior to July 14, within the 14 days allowed by F.R.A.P. 40(a)(b); Otero completed his petition for rehearing, whose main legal arguments were that a similar and applicable *"product liability"* case, *"Cipollone* v. *Liggett, Inc.*, 112 S.Ct. 2608 has been decided on June 24, 1992, during the *"pendency of appeal"* case 91-1987 and that as such, Court of Appeals should reconsider its *"Judgment"* of June 29, 1992 under the light of the intervening, (timely), U.S. Supreme Court Decision, a *"supervening change in the law"*, *prior* to and not *after "Judgment"* of June 29, 1992.

The *Petition for Rehearing* was *denied* on September 2,

1992, without taking into consideration "*Cipollone*" judicial factors. (112 S.Ct. 2608) even though Court of Appeals *granted* then appellant Otero's *supplementary legal arguments* in support of his Petition for Rehearing. (Appendix A, A-6)

Cipollone, therefore, was disallowed as a vital judicial factor, though timely alleged by the appellant Otero. Each and every legal argument used by Court of Appeals is superseded by 112 S.Ct. 2608. Petitioner Otero still alleges same on the basis of a "Case Law" relied upon in this Petition.

That is why this "*Petition For Writ of Certiorari*" is filed at the Honorable Supreme Court for the United States of America. (S.C. Rule 14.1 at (g). *Cipollone* v. *Liggett Group, Inc.*, 112 S.Ct. 2608, n.22, n.23, n.25, n.28, S.C. Rule 14.1 at (i); Title 28, Section 1332, Diversity of Citizenship.

The central issue in case 87-278 (JAF) was that co-defendants General Electric and Mallinckrodt held steadfastly to the following three defenses under oath:

(1) there is nothing in the medical literature that demonstrates patients with Urticaria Pigmentosa-mastocytosis, are prone to have lethal reactions when challenged with Conray 60. (Appendix E) Nor is the mast-cell prone to liberate histamine when challenged with Conray 60 and cause a lethal reaction.

(2) had the patient, Ruben Otero, been treated with LOCM (low osmolality contrast media), his prospects of surviving would have been no better than with Conray 60, or Hexabrix, for example, a LOCM product, because safer LOCM was not a proven "fact", notwithstanding the fact that McLennan so "proved" *prior* to trial and concealed it at trial. (Appendix D) So did Dr. Edward Aten, another expert witness for defendants.

(3) if the reaction were to be explainable at all, it would be because patient was asthmatic when he was a child, (he died at 34) and that was the cause of the reaction, his reaction to Conray 60.

The only thing wrong with those three lines of defense, is that Parker, Charles, W., M.D., and Bruce McLennan, M.D., wrote Medical Literature *exactly* to the *opposite* effect and came to San Juan, Puerto Rico's Federal District Court for the United States of America, to the Honorable District Court, to, through trickery and misrepresentation, so engage the Honorable District Court, under concealment, conspiracy and fraud, all the way to the Honorable Court of Appeals, before "*Cipollone*" supervened and became a Supreme Court landmark case.

The medical literature alluded to, is specified in *Appendix D ante*, with highlights of testimonies pro tem, which First Circuit Court of Appeals did not consider a "*genuine, thoroughgoing inconsistency,*" and, naturally, became oblivious to any *abuse of discretion* on District Court's part. [See Footnote 2]

REASONS FOR GRANTING WRIT

To the sound discretion of the Honorable Supreme Court, Petitioner states and prays that this Writ of Certiorari be granted on the following grounds:

1) *Cipollone* v. *Liggett Group, Inc.*, 112 S.Ct. 2608 (1992) at n.22, n.23, n.25, n.28, in particular but not exclusively, which were disregarded entirely by Court of Appeals. In addition, grounds of fraud per Title 31, L.P.R.A., Section 3018, as part of the "*Duty not to Deceive*" was also overlooked by Court of Appeals, who did not examine the Medical Literature Articles written by expert witnesses, Drs. Parker and McLennan, as well as verbal testimonies of Drs. Aten and Lazaga, under the light of 112 S.Ct. 2608 (1992). (Appendix D)

2) As in *In Re Bendectin Litigation*, 857 F.2d 290 (8th Circuit 1988) proposed at page 297, fn.5, the Honorable

Supreme Court has not yet made a definitive ruling on the possible creation of private rights of action based on Title 21, U.S.C., F.D.C.A. regulations on the *device* and *drugs* (ethical) field it occupies. Neither the GE CT 9800 nor Conray 60, are approved by the F.D.A. (*In re Bendectin Litigation*, 857 F.2d 290, 297 n.5 (6th Cir. 1988)) *Pappas* v. *Upjohn Company*, 926 F.2d 1019 (11th Cir. 1991)

3) Each and every case law the Court of Appeals cites in its judgment has been superseded by *Cipollone* v. *Liggett Group, Inc.*, 112 S.Ct. 2608. [Footnote 4]

4) *Court of Appeals did not manifest itself on Federal Rules of Evidence 803 at 18, the issue at District Court trial, and in so doing, blessed District Court's oversight.* (Appendix C)

5) General Electric did use at a point in time, Dr. Angel Roman Franco, as an expert witness. So did Mallinckrodt. General Electric, perfunctory, and on the threshold, also used Dr. Lazaga and Dr. Parker, as witnesses in cross-examination. Because General Electric and Mallinckrodt's strategy was based on examining witnesses in a shared manner, Court of Appeals was confused in determining who was whose witness on appeal. (Appendix A)

6) Stipulation ($100,000.00) settlement between co-plaintiffs and defendant Mallinckrodt, sounds more in contrast (bad faith based on fraud and conspiracy, concealment); n.25, n.28, 112 S.Ct. 2608) than in tort and was a *court determination urged* by Judge Fuste, unaware that he was to wrongfully dismiss a jury because he was subtly under the influence of fraud as influenced by the video-taped depositions in lieu of testimony where no Court official *was present* to *supervise* rule-wise, what *was to* become actual testimony. (Appendix A) (Appendix C) (*Cipollone* v. *Liggett Group, Inc.*, *supra*). [Footnote 3]

AMPLIFIED REASONS FOR ALLOWANCE OF WRIT

1. Package Inserts of 1986 (Conray 60) and 1989 (Conray 60) are contradictory in relation to "*Omnipaque*" a low osmo-

lality contrast media package insert, discussed in Case 87-278 (JAF), which is strong evidence on plaintiff's favor who alleged through trial, that LOCM is safer than HOCM. At trial, this was also *denied* vehemently by co-defendants expert witnesses, Dr. E. Aten and Dr. Bruce L. McLennan, even though the latter had written medical literature to the effect.

2. Although Court of Appeals steadfastly holds on to the alleged fact that General Electric didn't use any witness in District Court, the fact is they used Dr. Angel Roman Franco in a deposition prior to trial. Dr. Angel Roman Franco eventually became plaintiff's witness and as a matter of fact, was plaintiff's witness throughout trial at case (District Court 87-278 (JAF). (See Fn. (3) *"Application for Stay of Mandate", October 5, 1992*, U.S. Supreme Court. (Appendix B)

3. The fact that *"Federal Rules of Evidence"* 803 at 18 wasn't adhered to in this trial and Judge Fuste elaborates on the point, by not applying Rule 803-18, the doors were left open for not requiring as exhibits defendants nor plaintiffs medical literature in support of their expert witness testimonies, thus depriving the Honorable Judge Fuste of *essential evidence* upon which the case depended. (See Appendix C; *ante. As a matter of fact, the entire case depended on expert witnesses testimonies.* (Discovery & Experts, 38 F.R.D. 111)

4. Besides the evidence of *"Fraud"*, the U.S. Supreme Court decision, 112 S.Ct. 2608, and *"Safe Medical Devices Act of 1990"*, F.D.A. are the strong legal arguments which the Court of Appeals overlooked or merely took cognizance of, without acting upon them; petitioner Otero has reason to rest *"The Petition For Writ of Certiorari"* on the arguments brought forth above, within the limits of S.C. Rule 10 at .1a and .1c, respectively stating grounds for jurisdiction to the Honorable Supreme Court.

CONCLUSION I

"Safe Medical Devices Act of 1990", P.L. 101-629, November 28, 1990, 104 Stat. 451 L.

At Section (2)(B), (5), (A); *"Safe Medical Devices Act of 1990"* . . . The Secretary by regulation may include an out patient *diagnostic* facility which is not a physician's office, in such term.

This is exactly the factual situation in appeal case 91-1987, where Dr. Lazaga's (the practitioner radiologist who injected Conray 60 on patient Otero) diagnostic facility (Central C.T. Scan & Diagnostic Facilities, P.O. Box 3670, Hato Rey, Puerto Rico 00919) is the *"Device user facility"* who has leased to/from General Electric, a GE CT 9800 and injects Conray 60 for patients from Hospital Auxilio Mutuo in Hato Rey, Puerto Rico, in diagnostic procedures under contract with said Hospital.

It is petitioner's allegation, per Section 4, *"Safe Medical Devices Act of 1990"*, under (a) Section 513(f), (21 U.S.C. 360c(f) as amended by adding at the time, the following:

(3) If a manufacturer reports to the Secretary under Section 510(k) that a *device is substantially equivalent to another device*

i. which the Secretary has classified as a Class III device
ii. which was introduced or delivered for introduction *before* December 1, 1990, and
iii. for which no final regulation requiring pre-market approval has been promulgated under F.D.A. Section 505; is *misbranded per K841997*, Letter submitted to General Electric by the F.D.A., 1984 (Appendix F) (Appendix H)

(See Section 12; Substantial Equivalence); *(Safe Medical Devices Act of 1990)* (Appendices F & J)

Because the manufacturer has not accomplished nor complied with Section 4, Substantial Equivalence: Classification Revision and did not so do by concealing from the F.D.A.:

(1) That Radio Contrast Media, in this case Conray 60, is a *"combination product"*, *"accessory device to the GE CT 9800,"* and that such a combination accessory device is a hazardous substance, which is not only subject to regulatory controls on the part of F.D.A. since May 28, 1976; and the enactment date of the Medical Device Amendments (See Fn. (2), supra), also is hazardous to mast cells which every human being has by the millions or mast cells normalcy altered numbers, or patients with urticaria pigmentosa; and such information is absent on the Conray 60 package insert; and where *"Caution: Federal Law Prohibits dispensing without a prescription"*, the guiding medical literature because the package insert includes not the mast cell, urticaria pigmentosa situation, it would be lacking in an adequate and fully explained warning according to the scientific and medical community; and because Section 360j(e); Conray 60 an accessory diagnostic drug and the CT 9800 are *"Restricted Devices"* regulated by such Section of the F.D.A.; (Section 16, *"Safe Medical Devices Act of 1990"; Review of Market Applications for Articles Comprising Combinations of Drugs, Devices and Biologics,"* (Appendices F & J, *ante)*

Petitioner Otero alleges that both the GE CT 9800 and Conray 60 cannot be granted final approval by the F.D.A. without taking into proper consideration, case number 87-278 (JAF), Federal District Court of Puerto Rico, and appeals case 91-1987, U.S. Court of Appeals for the First Circuit, as allowed by Section 505; F.D.A. 38 F.R.D. 111 *supra.*

CONCLUSION (2)

The main factor in the *"Statement of the Case"* (1) (2) for this Petition is that in *"Per Curiam"*, June 29th, 1992, *"Court of Appeals"*, states at bottom of page 5 and top of page 6, that there are no *"other reasons justifying relief from judgment."* That conclusion does not take into consideration, U.S. 90-1038's *"Supervention"* of June 24th, 1992, a *supervening change in the law*. (112 S.Ct. 2608)

"Court of Appeals" does not say in a *"genuine thoroughgoing consistent manner"* that of such stuff, precisely, is Rule 60(b)(6) made . . . so as to allow for the inclusion of *"supervening changes in the law"* where public interest is enhanced without using rule artifacts of any nature whatsoever. Such a *"supervening change in law:* is provided by 112 S.Ct. 2608 fortuitously, insofar as appeals case 91-1987 goes, and the pre-empted and unpre-empted claims are to be determined by the Honorable Supreme Court upon review of petitioner's allegations. Please *bear* in mind for Rule 60(b)(3) and 60(b)(6) purposes, that a trial is a continuum from District Court, to Appeals Court to the Supreme Court, even if implicitly and even if most cases do not go through the full *continuum*. Supervening changes in the law within the continuum are integrated, thus, within F.R.C.P. Rule 60(b)'s scope.

Therefore, 60(b)(6) prevails, instead of 60(b)(3), as plaintiff petitioner has already said throughout District Court, Court of Appeals and now at the Honorable Supreme Court, pro se, petitioner Otero states and prays. Moreover, if F.R.C.P. 60(b)(6) were *not* to apply, F.R.C.P. Rule 60(b)(3) still applies tolling time one (1) year count-down, starting from June 24, 1992, which is the date U.S. 90-1038 intervenes as a supervening change in the law, *ergo*, 60(b)(3) *mootness* would prevail on June 24, 1993. (Cipollone, *ante* n.22)

At page 5, *per curiam*, fourth paragraph, prior to the last line, Court of Appeals determines the following:

> — "The District Court would have acted well within its discretion to conclude that Otero's filing did not point to the kind of glaring contradictions that might conceivably suggest possible misconduct. . . ."

Court of Appeals so concluded upon the alleged merits of finding "abuse of discretion" on District Court's determination.

Elementary at law is the non-feasibility of retroactive concessions to Trial Court on the basis of *evidence* which was not before the Trial Judge. Setting aside the argument of whether the medical publications by expert witnesses denoted any "*genuine thoroughgoing inconsistency*" which is the basic issue on appeal, it is implicit and of evidentiary foundation *priority*, that Trial Court examine the medical literature in question, which it chose, neglectfully, to overlook by tantalizing Federal Rule of Evidence 803-18, only to end up in giving up its application. (Appendix C)

What Court of Appeals is doing, is trying to fill the "vacuum" created at Trial Court, by not applying F.R.E. 803-18 although Judge Fuste toyed with it for a while and instead of on appeal, so doing, allowed the Court of Appeals to "retrospectively" *insert* the nature of the evidence which should have been presented at trial. Thus, petitioner states that Court of Appeals has exceeded its appeal function in fitting in, belatedly, a missing piece of evidence, after which "Court of Appeals", nevertheless, dismisses the appeal but cannot, even though try it did, dismiss the *nature* of the appeal, by inserting retroactively, evidence which was never presented at trial. This state of events is also submitted to the Honorable Supreme Court for review, very respectfully indeed, and again, petitioner pleads, a reason for remand and determination of mistrial in case 87-278 (JAF) District Court, as well as First Circuit Court of Appeals.

The medical literature was necessary to decide District trial (87-278). The nature of the trial was dependent exclusively

on expert witnesses' testimonies and *medical literature Foundation*. Court of Appeals had to determine upon challenging Medical Literature with testimonies, whether there were contradictions of value. "Court of Appeals reveals inadvertently, I should think, or forgets, or regretfully overlooked the fact that the medical literature was never presented in evidence, though Attorney Lopez-Romo pressed for said evidence at trial court and the plaintiff, Otero, "briefed" on it at "Court of Appeals". Furthermore, the F.D.A. was brought into trial picture in violation of fair trial to parties (due process clause) by co-defendants, allowed by Judge Fuste, without evidentiary material, thus giving grounds for a mistrial. Court of Appeals did not review at all the F.D.A. allegations. (*In re Bendectin Litigation, supra.*

"Court of Appeals" indirectly or based on a hurried foundation, however, brings forth the fact that such evidence *was* never presented at trial court; (87-278) and suppression of such evidence at trial, set aside appeal, provides grounds for mistrial; a basic, if not the most basic allegation for the Honorable Court to decide with particular attention to the fact that a jury was dismissed by the Trial Judge, as a result of such action, which *prior* to dismissal, had in the *absence* of such evidence (expert witnesses medical literature) forwarded Honorable Judge Fuste, to URGE a settlement stipulation . . . based on a legal vacuum, while caught on a spinning wheel spree, which only the Honorable Jury could have wrenched upon the presentation by expert witnesses, of their *medical literature*, as required by Federal Rule of Evidence 803-18 which wasn't relief upon by District Court nor reviewed by Court of Appeals. (Appendix C, A, p. A-6)

CONCLUSION (3)

Petitioner, granted not or granted relief, is now making the United States Supreme Court, the *"safe deposit vault"* of the information contained in this Petition. S.C. Rule 14.1 has

been completely adhered to herein, in harmony with the highly complex yet understandable nature of this Petition For Writ of Certiorari.

> — "If man were the more normal, healthy and happy, the more he can . . . successfully . . . repress, displace, deny, rationalize, dramatize himself and DECEIVE others then . . . it follows that the suffering of the neurotic comes . . . from *painful truth* . . . Spiritually, the neurotic has been long since, where psychoanalysis wants to bring him without being able to, namely, to the point of seeing through the deception of the world of sense, the falsity of reality. He suffers not from all the pathological mechanisms which are physically necessary for living and wholesome (sic) but in the refusal of these mechanisms which is just what robs him of the illusions important for living. . . ."
> —"(He) is much nearer to the actual truth psychologically than others and it is just that from which he suffers." . . .

OTTO RANK (1) "THE DENIAL OF DEATH," The Free Press, New York, Pulitzer Prize Winner ERNEST BECKER, (1924-1974).

FREEDOM OF EXPRESSION (AMENDMENT I)

Justice Oliver Wendell Holmes, during his memorable tenure at the Honorable Court, in relation to this *"Petition for Writ of Certiorari"* made a household, a coined phrase, an icon of jurisprudence of what then was "legal rationale"; "No-one shall *shout* fire in a movie house . . ." and then invoke *"freedom of expression"* as embodied in the First Amendment of the Constitution of the United States, as a defense to his or her excess, which may have led to *pandemonium*. Limits and definitions of "freedom of express" thus became clear on case law.

"Freedom of expression" Justice Holmes thus held, is limited and should be as such, *restrained*.

Guevara v. *Dorsey*, *supra*, is a United States First Circuit Court of Appeals Decision where though not addressed, *"freedom of expression"* on a collision course collides and creates an explosion of *"bad law."*

On the one hand, one has the *"freedom of expression"* rights of the manufacturer as restrained by regulations, in this case, F.D.C.A. (F.D.A.) within and not out of bounds of the provisions of the First Amendment.

On the other hand, the *"freedom of expression"* of the medical practitioner in practicing the art of medicines, directly regulated by the manufacturer's package insert, which in turn is regulated as I said before, by the F.D.A. causes collision, the explosion and the resultant faulty case law.

To uphold that a *"warning"* is not necessary, as *Guevara* v. *Dorsey* does, when a practitioner *"knows"* beforehand, what the *"warning"* is about and therefore, conclude that the *"warning"* is unnecessary is to induce the medical practitioner to pole-vault without a cushion to rely on.

Furthermore, within the strategic maneuvering that goes on in every trial, it is impossible to avoid ex-post facto, accommodating one's arguments within the *"case law"* which so allows during discovery. Accepted is the proposal that within

that *(Guevara* v. *Dorsey)* field, the trial lives or dies and the case law will turn out to be the hammer that whams the nails on the sentence. Such was the case in *Otero* v. *General Electric*, #87-278 (JAF).

"Nobody has the right to shout fire in a movie house . . . except when there is a fire".

May I add; when there is a fire in a movie house, the opposite holds true and the first amendment cornerstone then becomes an *obligation*. You are not then supposed to merely *shout*, you are as a matter of fact, *bound* to *scream fire!* This becomes then, the *positive enactment* of the *freedom of expression* course of the first amendment, contrary to *only* Justice Holmes negative enactment to uphold the First Amendment as explained before.

Fire did break out when Ruben Otero Laborde was injected with R.C.M. (Conray 60) to enhance the vision of his brain structure as required by the General Electric CT 9800. And the manufacturer did not scream in the *WARNING*.

And, there was no restraint on the part of the regulatory functions because insufficient evidence had been provided by the manufacturer, Mallinckrodt and General Electric to the F.D.A. or for that matter, to make it worse, after the fact at trial fraudulent representations to compensate for the lack of so doing, were belatedly employed and successful tactically speaking.

And then, the fire turned out to be a killer. (the reaction)

And then, the medical practitioner is supposed to put out the fire.

When the firemen fail to put out the fire which they did not start, they are negligent because they guaranteed and are trained to so do; *put out fires!*

Far-fetched!

The medical practitioner did not *start the fire*. How could he guarantee putting it out?

The medical practitioner can't be held liable and subsequently negligent for failing to put out that fire.

The manufacturers, Mallinckrodt and General Electric, started the fire. While the medical practitioner was an instrument, accessory; blinded to the fact of what was about to occur, meekly he failed in trying to convey he "knew" the reaction would occur.

The fireman started the fire?

And, as the song goes, only a kiss could put out that fire . . . the kiss of death!

Where have you gone, Justice Holmes, a medical practitioner turns his lonely eyes to you!

WHEREUPON, on this 29th day of January, 1993, and to the sound discretion of the U.S. Supreme Court, petitioner Jose Otero, pro se respectfully states and prays that this *"Petition For Writ of Certiorari"*, be granted as requested, from San Juan, Puerto Rico, on the above date, upon the determination of the Honorable Supreme Court, that *"Petitioner's Brief on the Merits,"* will uphold the essence of this *"Petition For Writ of Certiorari"* to the United States Court of Appeals for the First Circuit.

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FOOTNOTES

Fn. (1)

1. General Electric Co.
2. Mallinckrodt Co.
3. Dr. Jose M. Lazaga; under contract with Hospital Auxilio Mutuo
4. Hospital Auxilio Mutuo
5. Jose Carlo, M.D. Under contract with
6. Hector Feliciano, M.D. Hospital Auxilio Mutuo
7. F.D.A.; Food and Drug Administration brought forth by co-defendants lacking plaintiff's right to rebuttal because District Court's failure to apply F.R.E. 803-18; and Fn. (5) at I, supra (e)

Fn. (2)

"Long-standing regulations of the Food and Drug Administration express a similar understanding of the relationship between required warnings and advertising that negates or disclaims those WARNINGS: A hazardous substance shall not be deemed to have met (federal labeling) reqirements (if there) appears in or on (41) the label; ***statements***, ***designs***, or other ***graphic materials*** that in any manner ***negates*** or ***disclaims*** the (required warning.) 21 CFR 8; 191-102 (1965.)" (***Cipollone*** v. ***Liggett Group, Inc.***, ***Supra***, at 2623. "***Fraudulent Misrepresentation***". 4th par.)

In this light, it seems quite clear that Petitioner's first theory of fraudulent misrepresentations is extricably related to Petitioner's first failure to warn theory, a theory that we have largely concluded is pre-empted by 5 (b). (112 S.Ct. 2608, 2623). The Honorable Supreme Court is called to Rule and determine whether the F.D.A. warning-label law ***shielded*** Mallinckrodt and General Electric from claims over the adequacy of health warnings, particularly when those warnings are fraudulently presented at trial. (See 503 (353) (a) at 4; F.D.C.A.; Title 21) ***Cipollone***, ***Supra***.

Petitioner alleges that defendant Mallinckrodt's fraudulent representation in their expert witnesses' testimonies, as compared to their medical articles on the subject (See n.25, n.28, 112 S.Ct. 2608), are inextricably related to "Petitioner's ***Failure to Warn***" theory in case 87-278 (JAF) (District Court) and Appeals case 91-1987, (1st Circuit) and are not pre-empted by "Caution: Federal Law . . . 503(b)(1)(B) (See F.D.A. Section) albeit in a fraudulent manner, ***per n.25, n.28, "Cipollone, U.S. 112 S.Ct. 2608*** and (See II ***Questions presented for review)***

"***Failure to Warn***" 112 S.Ct. 2608, at page 16, last line, "The F.D.A. Act does not however, pre-empt petitioner's claims that rely solely on respondents' testing or research practices or other actions unrelated to advertising or promotion." ***Cipollone, Supra*** at 2621.

Therefore, settlement stipulation between co-plaintiffs Otero and Mallinckrodt, Inc., is voiced as a legal argument or judicial factor to be used as an impediment of legal character in any forwarded appeal, on U.S.

Appellate Jurisdiction, *ergo*, as the First Circuit Court of Appeals held in its judgment, June 29, 1992; reaffirmed by *"Order of the Court"*, September 2, 1992. (See Sec. 503(b)(1)(B) at 4, F.D.A.) that the settlement stipulation was an impediment to relief. The Honorable Court is called to review the matter, prayerfully.

Thus, this allegation, supported by the legal rationale explained above, per 112 S.Ct. 2608, is very respectfully submitted to the U.S. Supreme Court, as one of among other allegations; withstanding, F.R.C.P. 60(b)(6).

"Insofar as claims under either of Petitioner's failure to warn theories — i.e. that respondents were negligent in the manner that they tested, researched, sold, promoted and advertised *"Conray 60"* as and in combination with the GE CT 9800. (See Highlights of the Safe Medical Devices Act of 1990, P. L. 101-629) Such claims are not pre-empted by the F.D.A., either. (Section 16) (4)(20), 104 Stat. 451 L.

Section 16 *"Review of Market Applications for Articles comprising combinations of drugs, devices, and biologics."*

"For example, if the primary mode of action of a device/drug combination product is attributable to the device component of the product, the Center for Devices and Radiological Health will be responsible for the premarket review." (See GE CT 9800, F.D.A. file, Appendix H.

Nevertheless, if the primary mode of action of a device/drug combination product is *attributable* to the drug component of the product, the Center for Devices and Radiological Health should still be responsible, if for the simple reason we are dealing here with a radiological device and a *radiological diagnostic drug*, as petitioner has already proved, infra, per F.D.A. Section *201* at *h. See, Legislative History, House Report No. 101-808, page 6310 in reference to diagnostic and treatment facilities.*

When one of these facilities has information that reasonably suggests that a medical device may have caused a patient's death, the facility must report the information to the F.D.A. and to the manufacturer, if known. *(Dr. Lazaga's Drug Experience Report, appendix A-172 attached, was filled out after Ruben Otero's death, to Mallinckrodt, Inc., 675 McDonnel Blvd., P. O. Box 5840, St. Louis, Missouri 63194, who in turn didn't forward it to F.D.A.)*

Section 201, *"Chapter definitions, F.D.A.* at (h)(2)(3), explains Conray 60 as a device, component, accessory; and at (2) *"intended for the use in diagnosis", enters into no principal chemical action and is not dependent upon being metabolized for the achievement of any of its intended purposes.* As such, Conray 60 is a diagnostic device drug. (Appendix G, pp. A. 118-124.

Therefore, in that sense, Conray 60 is more a drug than a device, so to speak, since it is not intended like other drugs, for chemical changes, but physical changes to satisfy the enhancement needs of the CT 9800, the function of a *diagnostic drug* (See Appendix F, *ante).*

As the hazardous substance Conray 60 is, and as a diagnostic device-drug, it does not comply *nor has not*, with Sec. 503, (b)(1), A, B, C, at 4. *"Caution: Federal Law Prohibits dispensing without a prescription; because Conray 60 is not a prescription" drug, nor sells "over the counter" at "pharmacies."* As such, "Conray 60" is *misbranded,"* per F.D.A. Section *503, 104 Stat. 451 L.* (Appendix F) (See Sec. 7 (1456) (a) and (b), title 21, F.D.A. and Secs. 301, a, b, c, d, j, p, o, f, (1, 2) (Sec. 304, id, Sec. 307) (Sec. 10 (1459) at (e)(1)

Instead, it is a diagnostic drug with which the radiologist injects the patient, doesn't read the warnings to the patient, *but to himself*, upon determining decision to inject without allowing the patient to read it. *Simply stated, had patient Otero read the package insert, and it had included urticaria pigmentosa (mastocytosis) in its warnings, and then signed an informed consent; then and only then, would the manufacturer have been shielded from legal action.* But that is not the case here. The fact is urticaria pigmentosa was not included in the package insert and even if it had been *so included* the patient wouldn't have had the opportunity to withdraw from the medical examination, not *because the Doctor practitioner was on the obligation to so do*, on his way to inform consent, *but* because in order to protect the patient through the package insert warnings, which is the whole purpose of *WARNINGS, BOTH TO THE PRACTITIONER and the patient, not to only one* of the Two; so as to leave the door open for the patient to walk out even if the doctor "forgets" to read the package insert to the patient; the urticaria pigmentosa warning has to not only be included in the insert, but given to the patient to read. Then and only then, can it really be proven beyond doubt, that Urticaria Pigmentosa is a well-nown risk to R.C.M. Conray 60 patients and not by a *"blitz"* of hearsay in the medical community, *dubious* as that is, of which the patient has no knowledge whatsoever, because of the "Restrictive Device" nature of R.C.M. Only the practitioner *"knows"* after the death-knell of Radio Contrast Media, perfunctoily, enters the picture; namely the *"mast cell"* which every human being has and not only patients with Urticaria Pigmentosa. (Appendix E)

As the Honorable Court will see on "Briefs", if Certiorari is granted, all of defendants' defenses are mainly based on the alleged fact that Urticaria Pigmentosa patients are not prone to R.C.M. reactions, thus, a WARNING IS NOT NEEDED in the package insert, exactly because of the above, as Sec. 503 IMPLIES the patient is not given the insert to read. Further impeded because of the Restricted Device nature of the package insert, the patient never has to his advantage a "prescription" or "over the counter" drug package insert, per Sect. 503, *supra*, for him to READ, and *walk out.*

My allegation, Honorable Justices, is the following:

DO THE PATIENTS KNOW in the case of a Restricted Drug, such as Conray 60, what the package insert CONTAINS as distinguished from a "prescription" or "over the counter" drug? package insert? NO. (FDA § 520(e)(i)) 21 U.S.C. § 360j(e).

And, as a *sub-question* implied in the above, very simply I state, patients with *Urticaria Pigmentosa* may know of the DANGER, LIFE-THREATENING AT THAT, *ONLY* if its warning is present in the package insert, whether the medical community knows it or not. It is *NOT* after all, the Doctor (Practitioner) who is going to inject *himself*, but a patient *unaware* of what's going on behind the *"line of scrimmage,"* concealed by the diagnostic drug nature of Conray 60. 21 U.S.C. §360j(e)(1); Section 520(e)(1)

There is regulatory action for such a diagnostic device drug on the F.D.A. Law and certainly there is no remedy directly afforded to the patient who truly doesn't know what he is getting into. That's negligence describing why and when the "product is liable" under *"Restricted Devices"*, Sect. (F.D.A.) 503, (353)(b)(1)(B) at (4) not complied with by both GE CT 9800 and Conray 60, and F.D.A. (section 520(e)(1)). 21 U.S.C. §360j(e)(1)

At page 4, under *"warnings*, Conray 60, Revised Package Insert: 11/86 there is no mention of *non-toxic* contrast media even though Hexabrix a non-ionic osmolality contrast media was in the market on February 21, 1986 and is a Mallinckrodt product and Mallinckrodt per Dr. McLennan's, their own expert witness, has determined *Hexabrix* was safer than Conray 60. (See "Low Osmolality Contrast Media." (Premises & Promises) (See Appendix D, *ante* (See also I(a) *Questions presented for Review*, supra.)

At page 4, *Warnings* Conray 60, Rrevised 3/89, Package Insert: (1) "Ionic iodinated Contrast Media inhibits blood coagulation, in vitro, *more* than non-ionic contrast media"; is the opening *Sentence*. What Mallinckrodt denied in and prior to 1986, package insert Conray 60, is now admitted *after* case 87-278 (JAF) in October 9, 1988, just as witness McLennan wrote *prior* to case 87-278 (JAF) (Appendix D) . . . belatedly, thus Mallinckrodt *dated* the insert after case 87-278 (JAF) and McLennan's and Aten's testimonies, notwithstanding.

At page 8, "Omnipaque", a Winthrop Pharmaceutical product (iohexol; *non-ionic* low osmolality contrast media, reads under *"Warnings:* General) "Non-ionic iodinated contrast media inhibit blood coagulation IN VITRO *less* than ionic contrast media." (Revised August, 1990; after Conray 60; 3/89)

Therefore, *"Conray 60"* and *"Omnipaque"* agree, as we shall see later on, that Low Osmolality Contrast Media is *less* hazardous than High Osmolality Contrast Media, after expert witness Bruce L. McLennan M1) for Mallinckrodt and General Electric wrote a medical literature article *"Low Osmolality Contrast Media"; "Premises and Promises"*, where he agreed with the above, but conspired and concealed it from the Honorable Court, through legal maneuvering and fraudulent misrepresentation, as dependent on F.R.E. 803-18 *aptly* manipulated by Attorney Escalera for Mallinckrodt, and then testified; McLennan, said, among other things, that he didn't know what *"osmolality"* is, under oath at Trial. (Appendix D)

Fn. (3)

Per *Cipollone* v. *Liggett Group, Inc.*, "The effect of Tort Law . . . n.23, (112 S.Ct. 2608); n.25; n.28; *"misrepresentation"* and *"fraud" cannot lead (fraudulently) to a settlement stipulation insofar as: failure to warn"* which in (case 87-278 (JAF) is what plaintiffs settled; particularly when: "good faith", sounding in *contract* more than in *tort*, has an element lacking contract-wise (Justices Blackmun, Kennedy and Souter, 112 S.Ct. 2608), and furthermore the federal statute regulation in F.D.A. Law of *"Caution: Federal Law Prohibits dispensing without a prescription,"* for reasons explained before, (Questions presented for Review at I(d); has to be instead *"Warning"* or *"Caution"* per (h) the word *"poison"* for any hazardous substance which is defined as highly *"toxic"* by sub-section (h); which have been transferred under the Federal Hazardous Substances Act (11 U.S.C. 1261 et seq.) to the *"Consumer Product Safety Commission"*, (*Cipollone, Supra* at n.23) 24, Hon. Jusice Blackmun "The Effect of Tort Law on a manufacturer's behavior. . . ."

The functions of the Administrator of the *"Environmental Protection Agency"* and the *"Section of Health Environment and Welfare under the Acts"* amended by sub-section (b) through (f) of Section 7 of the *"Poison Prevention Act"* (Packaging) of 1970 (Act Dec. 30, 1970; P.L. 91-601, which, inter alia, amended U.S.C.S. § 1261 to the extent that such functions relate to the administration and enforcement of the *"Poison Prevention Packaging Act of 1970"* (15 U.S.C. 1461 et seq.) are transferred, thus to the *"Consumer Product Safety Commission."* (But see Section 502; o, p, q as amended, Title 21; F.D.C.A.) (Appendix G)

Petitioner Otero is not going into the intricacies of such statutes, but merely, arguendo, mentions them to demonstrate how *"ethical drugs"* regulated by the F.D.A. can some times border on *"poisonous"* substances, of which Conray 60 is an example because of its *toxity* directly related to its osmolality. (See Section 503 (353)(A)(B)(1) at (B) F.D.A.)

It is held, Section 503, *supra*, at 503(b)(1)(B) at (4), that a drug to which paragraph of this sub-section does not apply, shall be deemed to be *misbranded*, if at the time prior to dispensing its label bears the *"Caution"* statement worded in the preceding sentence.

Conray 60's vial does bear the *"Caution"* statement. It thus follows that it is *"misbranded"*. Conray 60's package insert does not mention the *"Caution"* statement. Petitioner alleges that the Conray 60 package insert is a *privy* affair between the manufacturer and the practitioner and same package insert promotes no interaction to the patient's benefit of having been warned as before stated and alleged in this petition.

However, 21 U.S.C. § 360j(e)(1), F.D.A. *"Restricted Devices"* at A and B, provides regulation for the case at hand.

Therefore, such section, *"Restricted Devices"*, regulates both the GE CT 9800 and Conray 60 as the restricted devices and diagnostic drug, as well as *accessory* or *component* they respectively are. Differently from *"prescription"* and *"over the counter drugs"*. So does Section 505, F.D.C.A.

Because the F.D.A. has considered Conray 60 a drug and not a diagnostic drug device, Petitioner, without withdrawing his allegation that Conray 60 is truly nothing but a *"Restricted Device"*, not subject to caution statements and therefore neither to WARNING statements, per Section 520(e) 1, *supra;* submits to the consideration of the Honorable Supreme Court, that case 87-278 (JAF) and appeal case 91-1987 are *moot* because in disregard of the pertinent evidence not present at trial, grounds for *mistrial* arise. Particularly when faced with the fact that Attorney Lopez-Romo raised the issue at trial and was disallowed by the Judge, specifically, that a warning has no value unless it reaches the patient, with all inclusive medical reasons that require a *"WARNING". (Trial Transcript*, page 390, Vol. II, lines 12-21) Mr. Lopez also asked for exhibits of co-defendants' expert witnesses; (Medical Literature exhibits), and Attorney Escalera for Mallinckrodt refused to comply.

This legal standing of Conray 60 before the F.D.A., ab initio, mishandled by the F.D.A. approval process, essentially because it treated Conray 60 as a Class I Device, at times, or as a Common Drug, as if it could be upon prescription, written or oral, acquired over the counter at a pharmacy. And, let's not forget, Honorable Justices, plaintiffs didn't raise the F.D.A. issue; co-defendants, did.

However, and without detracting from the above allegation, there is no final approval letter for Conray 60 from the F.D.A. Conray 60 has not had a *"New Drug Application"* (abbreviated) 21 C.F.R. 314(1)(f) and is subject, since August 8, 1977, to regulatory action because Mallinckrodt in marketing prior to approval of a new drug application, will and did, subject Conray 60 to regulatory action under F.D.A. Section 505. *(Federal Register Vol. 4, No. 161, Friday, August 19, 1977).* (Appendix J)

Fn. (4)

Cases cited in its *"Judgment"* by the U.S. Court of Appeals, which are *superseded*, allegedly, by U.S. 90-1078. (112 S.Ct. 2068)

(1) *United States* v. *Marin*, 720 F.2d 229-231, (1st Cir. 1983)

(2) *United States* v. *Boch Oldsmobile, Inc.*, 909 F.2d 657-660 (1st Cir. 1990)

(3) *Rodriguez-Aetna* v. *Chase Manhattan Bank Corporation*, 871 F.2d 1-3 (1st Cir. 1989)

(4) *Guevara* v. *Dorsey Laboratories Division of Sandoz, Inc.*, 845 F.2d 364 (1st Cir. 1988) (Appendix H)

Emphasis supplied on allegation these *"Cases"* are superseded by 112 S.Ct. 2608, and so shall be proven on "Briefs", were this Petition to get so far, because as a result of the alleged *"supervention"* Court of Appeals legal rationale is entirely invalidated and therefore, Appeal case #91-1987 should be remanded to Court of Appeals and subsequently to District Court for a new trial.